



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Jonathon Dinsmore

Serial No.: 09/163,272

Filed: September 29, 1998

For: *Porcine Spinal Cord Cells and Their
Use in Spinal Cord Repair*

Attorney Docket No.: DNI-041RCE

Group Art Unit: 1632

Examiner: Anne Marie Falk

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATION UNDER 37 CFR 1.10

Date of Deposit: February 14, 2005

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I hereby certify that this 37 CFR 1.53(d) request and the documents referred to therein as enclosed are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and addressed to MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Cristin E. Howley

Name of Person Mailing Paper

Signature of Person Mailing Paper

DECLARATION UNDER 37 C.F.R. §1.132 OF JONATHAN DINSMORE

I, Jonathan Dinsmore, a citizen of the United States of America, residing in Brookline, Massachusetts, hereby declare as follows:

1. I am presently Senior Director of Research at GenVec, Inc. (formerly Diacrin, Inc). I have been working in the area of cellular transplantation for approximately 13 years. A copy of my curriculum vitae is attached as Appendix H.

2. I have carefully read the above-referenced application (submitted herewith as Appendix I) and presently pending claims 1, 3-8, 10-18, 20-26, and 28-64 and newly added claims 65-69 (currently pending claims including amendments being submitted herewith as Appendix J). It is my understanding that the invention set forth in claim 1 pertains to a composition for transplantation into a mammalian xenogeneic subject suffering from a spinal cord injury or a neurodegenerative disorder resulting from a degeneration of cells of the spinal cord comprising isolated spinal cord cells obtained from an embryonic pig of between about 24 and about 35 days of gestation. I understand that the invention set forth in claim 18 pertains to a method of treating a mammalian xenogeneic subject having a spinal cord injury comprising administering to the subject a composition comprising isolated spinal cord cells obtained from an embryonic pig of between about 24 and about 35 days of gestation, such that treatment of the spinal cord injury is obtained upon administration of the composition to the subject, wherein the spinal cord cells or the subject are treated to reduce an immune response to the cells of the subject. It is also my understanding that the invention set forth in new claim 65 pertains to a method of treating a mammalian xenogeneic subject having a neurodegenerative disorder resulting from degeneration of spinal cord cells comprising administering to the subject a composition comprising isolated spinal cord cells obtained from an embryonic pig of between about 24 and about 35 days of gestation, such that treatment of the neurodegenerative disorder is obtained upon administration of the composition to the subject, wherein the spinal cord cells or the subject are treated to reduce an immune response to the cells of the subject.

3. I have carefully read and understood portions of the most recent office action in the above-identified application, in particular the rejection of record of claims 1, 3-8, 10-18, 20-26, and 28-48 which have been rejected under 35 U.S.C. 112, first paragraph as set forth at pages 2-4 of the Office Action (attached as Appendix K). It is my understanding that the Examiner is taking the position that no evidence has been submitted which offers support that the protocol submitted in Applicant's response of May 24, 2004 was used to produce the results referred to in the previous Declaration filed on January 16, 2003 (hereinafter the "first Dinsmore Declaration").

4. I have carefully read and understood the protocols submitted herewith as Appendix F and the procedural reports submitted herewith as Appendix G of the instant Declaration.

The protocols enclosed in Appendix F herewith correspond to each of the subject ID numbers, *i.e.*, SRL-05, LDS-04, WDS-03, CLO-02, and CCD-01, mentioned in the results described in Appendix E of the first Dinsmore Declaration. The protocols enclosed in Appendix F herewith are identical and were provided to the physicians performing xenogeneic transplantations in accordance with the claimed invention, the results of which are described in the first Dinsmore Declaration. The protocol for subject ID number WDS-03 was also submitted previously in Applicant's response of May 24, 2004.

The attached protocols show that porcine spinal cord cells were administered directly to the spinal cord of the subjects in the clinical trials. The physicians were instructed to suspend the cells prior to administration, and then told to directly inject the cell suspension into the spinal cord of the subject. As shown in Appendix F, the

instructions note that the number of injections warranted for individual transplantation procedures depended upon the extent of the spinal cord damage.

As evidence that the protocols enclosed in Appendix F, in accordance with the teachings of the above-referenced application, provided sufficient guidance for one of ordinary skill in the art to make and use the claimed invention, procedural reports from each subject are enclosed as Appendix G. The procedural reports provide a summary by the physician performing each xenotransplantation of the actual procedure used. As shown in Appendix G, each report includes information regarding the number of injection sites, and the location of each injection site, and the volume of cells injected into the subject from which one can determine the number of cells based on the description in the protocols of Appendix F, which state that 20 microliters "is equal to 2 million cells".

The protocols described in Appendix F are consistent with the teachings of the above-referenced application and were used to successfully treat patients having a spinal cord injury or a neurodegenerative disorder resulting from a degeneration of cells of the spinal cord, as shown in the first Dinsmore Declaration. Accordingly, the protocols and reports described in Appendices F and G correspond to the protocols used to produce the results submitted in the first Dinsmore Declaration which demonstrate that transplantation of xenogeneic porcine spinal cord cells can be used effectively as treatment for improving both the sensory and motor function of human subjects having spinal cord injury or a neurodegenerative disorder.

5. The transplantations performed according to the protocols described herein in Appendix F, were done using masked cells to reduce the likelihood of rejection of the porcine spinal cord cells in the human recipient.

6. It is my opinion that one of ordinary skill in the art at the time the above described invention was made, having carefully read and understood the experiments presented in the specification of the above-referenced application and being armed with the knowledge available to those of ordinary skill in the art, would have been able to use the claimed invention commensurate with the scope of the claims. It is also my opinion that the protocols described in enclosed Appendix F are commensurate with the teachings of the specification.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Jonathan Dinsmore
Jonathan Dinsmore

2/14/05
Date